Healthcare Sector in Selangor
(Part II: Medical Devices)

New milestone for the healthcare sector

In line with SSIC Berhad’s review of the Healthcare sector, the previous reports *(Part I: Healthcare Providers)* highlighted already that private healthcare services have grown tremendously over the past decade. In order to further develop Malaysia’s healthcare infrastructure, besides continually seeking for initiatives to enhance collaboration between public and private healthcare providers, the Malaysian government is also encouraging more private investments in related industries such as medical devices, pharmaceutical products, clinical research, aged-care services etc.

This part II report will specifically focus on the medical devices industry in Malaysia and particularly in Selangor. It is worth mentioning that two major centres of healthcare and related industries exist in Malaysia. Selangor and the Klang Valley comprise one of the two focal points, while the other is Penang in the north of the country.
<table>
<thead>
<tr>
<th><strong>Population (2012)</strong></th>
<th>Malaysia</th>
<th>Selangor</th>
<th>Rank in Malaysia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>29.3 million</td>
<td>5.6 million</td>
<td>1</td>
</tr>
</tbody>
</table>

| **Average Annual Population Growth Rate (2012)** | 1.3% | 1.3% | 5               |
| **Average Life Expectancy (years)** | 74.8 (estimate) | 75.7 (estimate) | 4               |

| **GDP at constant 2005 Prices (2012, RM)** | 751,471 million (100%) | 176,239 million (23.50%) | 1               |

| **GDP Growth (2012)** | 5.6% | 7.1% | 2               |

| **Investment Volume (2012, RM)** | 41 billion (100%) | 11.7 billion (28.5%) | 1               |

| **Workforce (2012)** | 13.1 (100%) | 2.82 (21.5%) | 1               |

| **Market value of Malaysia Healthcare Sector (2012, RM)** | 6.96 billion | 2 billion (estimated) * | 30.0 % |

| **Total MoH Allocation (2012, RM)** | 16.87 billion | 2.1 billion | 12.4 % |

| **Market value of Malaysia medical devices industry (2013, RM)** | 3.7 billion (estimated) | NA | NA |

| **Number of AMMI Members** | 44 (Total medical devices manufacturers in Malaysia: > 180) | 20 | 46% |

**Incentives for Medical Devices**
- Incentives for companies investing in new testing laboratories for testing medical devices (applicable till 31 December 2012).
- Incentives for companies upgrading existing testing laboratories for testing medical devices (applicable till 31 December 2012).
- Exemption for import duty on imported medical devices for purpose of kitting
- Double deduction for the promotion of exports
- More details on page 19-22

**Useful Contacts**
- Medical Device Authority: [http://www.mdb.gov.my](http://www.mdb.gov.my)
- Malaysia Medical Device Association: [http://www.mmda.org.my](http://www.mmda.org.my)

*Figures as per Klang Valley, inclusive Federal Territories Kuala Lumpur & Putrajaya*
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1. **Overview of the Medical Devices Industry**

Malaysia’s healthcare sector has experienced robust growth over the past decade. Being a major economic contributor for Malaysia, the healthcare sector has been categorised as one of the 12 National Key Economic Areas (NKEAs) under the Malaysian Government’s Economic Transformation Programme (ETP). The programme targets to generate RM35.5 billion in Gross National Income (GNI) and create 181,000 new job opportunities by 2020. ETP has identified 13 Entry Point Projects (EPPs) for the healthcare sector, in which more than 50% of these projects are specifically focused on the medical devices industry (EPP 7-EPP 13).

<table>
<thead>
<tr>
<th>No</th>
<th>EPPs</th>
<th>Location</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>EPP 1: Mandating Private Insurance for Foreign Workers</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>2</td>
<td>EPP 2: Creating Supportive Ecosystem to Grow Clinical Research</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>3</td>
<td>EPP 3: Malaysian Pharmaceuticals – Increasing Local Generic Manufacturing for Exports</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>4</td>
<td>EPP 4: Reinvigorating Healthcare Travel</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>5</td>
<td>EPP 5: Creating a Diagnostic Services Nexus</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>6</td>
<td>EPP 6: Developing a Health Metropolis: A World-Class Campus for Healthcare and Bioscience</td>
<td>Selangor</td>
<td>Operational</td>
</tr>
<tr>
<td>7</td>
<td>EPP 7: Upscale Malaysia’s In-Vitro Diagnostic (IVD) Industry</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>8</td>
<td>EPP 8: Build Malaysian Showcase on Next Generation of Core Single Use Device (SUD) Products</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>9</td>
<td>EPP 9: Become the Hub for High-Value Medical Devices Contract Manufacturing</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>10</td>
<td>EPP 10: Malaysian Clinical Device Champions</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>11</td>
<td>EPP 11: Medical Equipment Supply Chain Orchestration</td>
<td>Penang</td>
<td>Operational</td>
</tr>
<tr>
<td>12</td>
<td>EPP 12: Medical Refurbishment Hub</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
<tr>
<td>13</td>
<td>EPP 13: Build Medical Hardware and Furniture Cluster</td>
<td>Nationwide</td>
<td>Operational</td>
</tr>
</tbody>
</table>

Table 1: List of Healthcare EPPs, Source: Economic Transformation Programme website 2013

**1) The Global Medical Devices Industry**

The global medical devices industry is one of the fastest growing industries in the world with an estimated annual market growth rate of
around 10%. According to “The World Medical Market Book 2013” by Espicom, the value of the global medical devices industry was US$327.7 billion in 2012, excluding in vitro diagnostic sales. This rapid growing industry is made up of more than 27,000 firms worldwide and provides job opportunities for approximately 1 million people around the world.

Due to low or moderate entry barriers, the competition within the global medical devices industry is fairly high. Reportedly, United States (US) is the world’s largest competitor, dominating nearly 36% of the global market. It is also the leading supplier of medical devices, housing 16 out of the top 30 medical device companies in the world.

<table>
<thead>
<tr>
<th>No</th>
<th>Country</th>
<th>Estimated Sales Revenue (US$ billion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>United States</td>
<td>118.9</td>
</tr>
<tr>
<td>2</td>
<td>Japan</td>
<td>32.4</td>
</tr>
<tr>
<td>3</td>
<td>Germany</td>
<td>23.1</td>
</tr>
<tr>
<td>4</td>
<td>China</td>
<td>14.1</td>
</tr>
<tr>
<td>5</td>
<td>France</td>
<td>13.5</td>
</tr>
<tr>
<td>6</td>
<td>United Kingdom</td>
<td>9.9</td>
</tr>
<tr>
<td>7</td>
<td>Italy</td>
<td>8.6</td>
</tr>
<tr>
<td>8</td>
<td>Canada</td>
<td>6.8</td>
</tr>
<tr>
<td>9</td>
<td>Brazil</td>
<td>6.8</td>
</tr>
<tr>
<td>10</td>
<td>Others</td>
<td>5.3</td>
</tr>
<tr>
<td></td>
<td>World Total (67 Countries)</td>
<td>327.7</td>
</tr>
</tbody>
</table>

Market Share:

Notes: 1. Revenue estimates are based on 67 countries 2. Excluding in vitro diagnostic sales

Although US still appeared to be at the top of the industry, in fact the country is facing extensive competition, especially from emerging markets. The medical devices industries of BRIC (Brazil, Russia, India & China) have grown rapidly in recent years, with a total market worth of US$26.2 billion in 2012. Interestingly, China has also moved up from No. 7 (2009) to No. 4 (2012) of the Top 10 Medical Devices Market ranking in a short period of time, and is forecasted to become the 2nd largest market by 2017.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Company</th>
<th>Country</th>
<th>Rank</th>
<th>Company</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Johnson &amp; Johnson</td>
<td></td>
<td>16</td>
<td>St. Jude Medical</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>GE Healthcare</td>
<td></td>
<td>17</td>
<td>Novartis (Alcon)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Siemens Healthcare</td>
<td></td>
<td>18</td>
<td>3M Healthcare</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Medtronic</td>
<td></td>
<td>19</td>
<td>Zimmer</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Baxter International</td>
<td></td>
<td>20</td>
<td>Terumo</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Philips Healthcare</td>
<td></td>
<td>21</td>
<td>Olympus Medical</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Covidien</td>
<td></td>
<td>22</td>
<td>Smith &amp; Nephew</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Abbott Labs</td>
<td></td>
<td>23</td>
<td>Hospira</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Cardinal Health</td>
<td></td>
<td>24</td>
<td>Toshiba Medical</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Stryker</td>
<td></td>
<td>25</td>
<td>Getinge Group</td>
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<tr>
<td>11</td>
<td>Danaher</td>
<td></td>
<td>26</td>
<td>CareFusion</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Becton Dickson</td>
<td></td>
<td>27</td>
<td>Bayer</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Boston Scientific</td>
<td></td>
<td>28</td>
<td>Fresenius Medical Care</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>B. Braun</td>
<td></td>
<td>29</td>
<td>C.R. Bard</td>
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<tr>
<td>15</td>
<td>Essilor</td>
<td></td>
<td>30</td>
<td>Dentsply</td>
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<td>16</td>
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<td>4</td>
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Table 2: Top 30 Medical Device Manufacturers in 2012, Source: Medical Product Outsourcing (MPO) 2013

The global medical devices industry covers a wide variety of products. These can be mainly categorised into five key business segments:

i. Consumables

ii. Diagnostic apparatus (e.g. MRI & CT-scan)

iii. Patient aids (e.g. hearing aids & pacemakers)

iv. Orthopaedic products

v. Dental products

vi. Other medical equipment
(2) The ASEAN Medical Devices Industry

Being one of the key regions of growth, Asia-Pacific is expected to reach approximately one third of the global medical devices market by 2015. According to Frost & Sullivan, the medical devices sector of Asia Pacific will grow from US$50 billion (2012) in revenue to more than US$106 billion by 2018. ASEAN, in particular, is a new hidden gem with great potentials. Currently, the ASEAN medical devices market is fairly under-developed with a total value of more than US$4 billion (approx. 1% of global market share) in 2012; where 65% of the US$4 billion are derived from Asia’s new tigers: Malaysia, Indonesia and Thailand. The ASEAN medical devices market value is also expected to double by 2017 reaching US$8 billion.

ASEAN Consultative Committee on Standards and Quality (ACCSQ) realised that the harmonisation of the medical devices sector and the efficiency of its regulations are both very crucial for the successful development of the ASEAN medical devices industry. Consequently, ACCSQ established the Medical Device Product Working Group (MDPWG) in 2004 to unify the standards in the industry regarding medical device registration and post-market surveillance throughout the ASEAN region. The most recent draft regulation – the ASEAN Medical Device Directive (AMDD) was published in 2012 and will put into implementation by December 2014 (estimated). However, AMDD is only a guideline for the member nations, which is not legally binding.

For classification, AMDD adopts a risk-based classification system based on global guidelines. Medical devices (including in-vitro diagnostics) can be categorised into below 4 types:
Healthcare Sector in Selangor
- Part II: Medical Devices -

i. Class A: low risk devices e.g. tongue depressors
ii. Class B: low-moderate risk devices e.g. hypodermic needles
iii. Class C: moderate-high risk devices e.g. lung ventilators
iv. Class D: high risk devices e.g. heart valves

The ASEAN Federation of Medical Industry (ASEANMed) was subsequently formed after the signing of the Memorandum of Understanding by seven medical device industry associations from Thailand, Philippines, Malaysia, Singapore and Indonesia, which acknowledged their commitment to advance medical device industry.

![ASEANMed](image1)

**To represent a single & unified voice of the ASEAN medical device industry**
**To promote ease of trade among the region**
**To enhance & professionalise trade**

![Luxury Medical Device Clusters in Malaysia](image2)

**Picture 1: The ASEAN Federation of Medical Industry, Source: ASEANMed website 2013**

**3) The Malaysia Medical Devices Industry**

Being part of the ASEAN region, Malaysia again has great potentials to become an ideal location for investments related to medical devices with an annual market growth rate of 8%-10%. As mentioned earlier, Malaysia healthcare sector is categorised as one of the NKEAs. With more than 50% of the Healthcare EPPs specially assigned to medical devices, it is obvious that the medical devices industry is a new target development area for the Malaysian
government. Currently, the two main clusters for the industry are located in Penang and Selangor. Another smaller cluster is emerging in Johor.

Similarly to the global market, Malaysia’s medical devices industry is highly diversified with a wide variety of products including medical gloves, implantable devices, orthopaedic devices, dialysers, diagnostic imaging equipment and other related devices (for medical, surgical, dental, optical & general health purposes). Nevertheless, a vast amount of medical devices until today is still acquired abroad or procured from multinational companies invested in Malaysia. The domestic industry is dominated by the production of rubber-based products (e.g. medical gloves & catheters). In order to remain competitive, Malaysia is gradually shifting towards the manufacture of non-rubber based medical devices made from plastics, silicone and metal alloys, which are higher in value. The Malaysian government has also encouraged domestic manufacturers to produce more advanced equipment e.g. diagnostic imaging equipment.

2. The Industry Performance in Malaysia

Despite having an estimated annual growth rate of 8%-10% in the Malaysia medical devices industry, the current estimated market value for 2013 is RM 3.7 billion (US$ 1.2 billion), which remains relatively low and is only equivalent to about 1% of the total US Market. Although Malaysia has recently started to implement its first set of regulations for medical devices, it is not expected to have an immediate effect on the market share and market growth in the near future. Therefore, medical devices market of Malaysia is expected to reach RM5.1 billion in 2015.

![Medical devices market in Malaysia](chart3.png)

Notes: The market value includes only the local consumptions, excludes exports
Chart 3: Medical Devices Market in Malaysia, Source: PEMANDU (NKEA), MIDA 2013
The domestic consumption of medical devices is still mainly driven by imports with more than 85% of the medical devices (especially high-end equipment) in Malaysia are being imported. Domestic manufacturers on the other hand focus more on rubber-based products (e.g. medical gloves & catheters). Malaysia is a world leading producer and exporter for catheters and rubber gloves, supplying up to 80% of the world market for catheters and 60% for rubber gloves (including medical gloves). Selangor state in particular, successfully housed a number of global leading brands in the rubber glove industry such as Top Glove, Hartalega Holdings, Supermax Corp. Berhad, Biomax Rubber Industries among others.

<table>
<thead>
<tr>
<th>Company</th>
<th>Expansion Plans</th>
</tr>
</thead>
</table>
| **TOP GLOVE**<sup>(1)</sup> | - Reportedly, it currently maintains a global market share of 25% and plans to expand this share to 30% (World's largest rubber glove manufacturer)  
- Invest RM3 bn (US$1 bn) in a 15-year expansion programme, involve several facilities worldwide  
- In Selangor: Top Glove Tower, a 23 storey office building in Setia City, Shah Alam |
| **Hartalega** | - Invest RM1.5 bn (US$ 580 million) to set up a world-class complex in Selangor with 6 factories and 72 high-tech production lines, which can produce more than 28 bn gloves a year and will employ up to 5,000 workers  
- Estimated completion year: 2021  
- Currently building its 10<sup>th</sup> and 11<sup>th</sup> factories |
| **Supermax Corp. Berhad** | - Invest RM52.6 million to set up its 2<sup>nd</sup> Malaysian glove manufacturing facility in Kuala Selangor |
| **BioMax** | - Invest RM52.6 million to set up its 2<sup>nd</sup> Malaysian glove manufacturing facility in Kuala Selangor |

Table 3: Top Rubber Gloves Manufacturers in Selangor, Source: MGCC Perspectives September 2013, Sun daily and Site Selection Magazine 2013

In 2012, Malaysia’s exports of medical devices reached RM12.9 billion. As mentioned earlier, medical gloves and catheters dominated and contributed RM9.8 billion of the total value, whereas electro-mechanical devices, contraceptives, ophthalmic lenses, radiation devices, orthopaedic implants and other instruments (for medical, surgical & dental practices) only made up of RM3.1 billion in total. Medical devices made in Malaysia were mainly exported to the US, Europe, Japan and Asia Pacific countries. The Association of Malaysian Medical Industries (AMMI) forecasts the exports to increase to RM13.7bil in 2013.
Nevertheless, the share of the medical gloves and catheters has slowly started to diminish as compared to the past years due to domestic manufacturers gradually shifting towards higher value added medical devices and the ecosystem surrounding this sector. As the global environment for the medical devices industry becomes more and more competitive, manufacturers are forced to expand their product base and invest more in R&D, as well as design and prototyping. In terms of quality, TÜV certifications and SIRIM are the two major certification bodies for medical devices in Malaysia.

Diagram 1: The Ecosystem of the Medical Device Industry in Malaysia, Source: Medsociate, AMMI 2013
(1) Current Structure of The Industry

Malaysia currently has more than 180 medical devices manufacturers including MNCs, LLCs and SMEs as shown in Picture 3. The medical devices industry is dominated by SMEs engaged in the production of medical gloves and other medical disposable products. The MNCs on the other hand are mainly involved in the production of higher value products.

Examples of Major Medical Devices Companies Operating in Malaysia
(2) Regulating the Medical Devices Industry

i. First phase: Medical Devices Registration Scheme (Voluntary basis)

The Malaysian Ministry of Health introduced the Medical Devices Registration Scheme by launching an electronic registration system – MeDVER on 12 January 2006, to encourage voluntary registration of manufacturers’ medical devices. The registration system was designed as a transitory step to ease transfer of the registered applicants to the mandatory registration process. However, there is no guarantee that the devices registered with MeDEVER will obtain approval under the new system.

ii. Second Phase: Medical Device Authority (MDA)

The Medical Device Authority Act 2012 (Act 738) came into effect on March 15, 2012 to establish a regulatory body for the medical devices industry in Malaysia. Subsequently, the Medical Device Authority (MDA) was established in August 2012 under the Ministry of Health Malaysia (MoH), charged with the role of regulating medical devices and its industry players. Besides, it is also responsible for enforcing and implementing the Medical Device Act 2012 (Act 737).

iii. Third Phase: Medical Device Act 2012 (Act 737)

As replacement of previous voluntary registration scheme, the Medical Device Act 2012 (Act 737) and Medical Device Regulation 2012 came into operation on 1 July 2013. Following the global harmonisation trend, the Act is aligned with the guidelines drawn up by the Global Harmonisation Task Force (GHTF), Asian Harmonisation Working Party (AHWP) and ACCSQ. The Act is also based on recommendations from the World Health Organisation (WHO). On the other hand, the Medical Device Regulation 2012 is a subsidiary legislation under the Act.

The Act introduces the requirement for all medical devices that are imported, exported and placed for sale in Malaysia to be registered. Similar with AMDD as discussed above, Malaysia adopts a four-tier classification scheme: Class A (lower risk), Class B (low to moderate risk), Class C (moderate to high risk) and Class D (highest risk). There will be a transition period of two years, from 1 July 2013, for medical device manufacturers to register with the MDA. The registration process again could be done electronically through Medical Device Centralised Application System (MEDCAST) (http://www.mdb.gov.my/medcast/login/).

In addition, the Act calls for all medical device establishments (manufacturers, distributors, importers, exporters, conformity assessment...
bodies and local authorised representatives, but not including retailers), to obtain an establishment license from the MoH. Unlike the device registration timeline, local manufacturers, importers, distributors and local authorised representatives will only have one year to obtain their establishment licenses.

This newly developed medical device regulatory system is very crucial to ensure compliance of Malaysia’s medical devices to the international standards of safety, quality and effectiveness. By creating a favourable growth environment and encouraging healthy competitions within the industry, Malaysia will slowly gain competitive advantage in the global marketplace. It may also attract more foreign direct investment and joint venture projects in the future.

For more information regarding the medical devices regulations in Malaysia, kindly download the related documents at the below link: http://www.mdb.gov.my/mdb/index.php?option=com_content&task=view&id=47&Itemid=103

(3) Medical Device Associations

i. Association of Malaysian Medical Industries (AMMI)

Location: Penang

The 44-members association was established in 1989 and includes a variety of leading medical device manufacturing companies in the medical technology industry. AMMI members involve 3 main industry players: manufacturers; suppliers of medical devices manufacturing companies; and importers & exporters. These companies continue to be the growth base of the medical devices industry in Malaysia with a total workforce of 25,606 people.

According to AMMI’s 2012 Industry Survey (67% response rate), its member companies collectively account for nearly 50% (RM5.9 billion) of the Malaysia’s total medical device exports (RM12.9 billion) in 2012. AMMI members target to achieve 8%-10% export growth in 2013. In terms of investment, AMMI members have increased their investments in domestic operations by RM400 million in 2012 compared with the previous year, with around RM44 million spent on R&D activities. With a steady increase of investment over the years, the accumulated investment amount has more than doubled, from RM1.5 billion in 2008 to RM3.2 billion in 2012.

Parallel with clusters distribution, AMMI member companies are mainly located at the Northern Corridor Economic Region (Penang, Kedah, Perak,
Perlis), Selangor and Johor. Among these locations, Selangor has the largest amount of AMMI members.

ii. **Malaysia Medical Device Association (MMDA)**

*Location: Selangor*

Established in 2005, MMDA is officially recognised by the Medical Device Bureau of MoH as the voice of the medical devices industry. Same as AMMI, MMDA has a variety of members including local manufacturers, local authorized representatives, importers, suppliers, distributors, multi-national corporations and sales representatives for medical devices within Malaysia. MMDA currently represents approximately 180 member companies.

3. **Potential Driving Forces in Malaysia**

(1) **Growth Factors**

i. **Harmonisation of ASEAN Medical Devices Industry**

ASEAN is currently very keen to promote harmonisation within the ASEAN medical devices industry. AMDD is estimated to put into implementation by December 2014, which will improve the medical device importation, registration and distribution regulations in the 10-member states region. Malaysia at the same time has recently enforced its first medical device regulation, which is aligned with ASEAN’s mission. This perfect timing placed Malaysia in a great position to further develop its medical devices industry and to exploit more opportunities in ASEAN as well as globally.

Moreover, the ASEAN Economic Community and further agreements on investment policies such as ACIA will standardise requirements to enter neighbouring markets, for both trade and investment. Therefore, Selangor being strategically located in the heart of Malaysia and ASEAN has the perfect combination of geographic location, labour and education as well as logistics and infrastructure to become the investment destination of choice of medical device companies.

ii. **Increasing Demand**

The demand for medical devices continues to rise, not only from the overseas markets, but the domestic markets as well. This is mainly based on the following demographic and developmental effects.
(i) Ageing Population

Life expectancy has jumped nearly 20 years over the past 50 years. The worldwide demographics are increasingly moving towards older population: between 2000-2050, population aged over 60 years in developed regions will grow from less than 20% to 34%, while the proportion of children aged under 15 years is set to decline by 2% from 18%. Same applies to Malaysia, the country will be classified as an ageing nation with at least 10% of its population aged 60 years and above by 2020 compared to the current 6%; by 2030, the population aged 60 years and above will further increased to at least 15%. As such, Selangor being the state with the most population will certainly face aging issues in the near future.

Generally, elderly requires more healthcare services. This demographic shift is an assurance for the medical devices industry of increasing market demand.

(ii) Urbanisation & Changes in Lifestyle

A more affluent society and changes in lifestyles have led to the creation of a robust domestic industry for medical devices. According to Frost & Sullivan, approximately 2.6 million people are expected to move from rural areas to urban areas in Malaysia between 2013 and 2018. Increasing urbanisation is accompanied by growing consumer awareness, expanding of middle class population and changes in lifestyle, thus resulting in a greater demand for improved healthcare services and medical devices. Although urbanisation is already very much accomplished in Selangor (91.4% in 2010), increasing construction activities and Malaysian’s leaving their villages for the convenience of an urban life-style within the state indicate that urbanisation is still an on-going process.

Furthermore, the availability of modern infrastructure encourages an unhealthy lifestyle among the society, which increases the risk of acquiring chronic diseases. According to “Statistics on Causes of Death” prepared by Department of Statistics Malaysia, heart diseases, pneumonia, diabetes, stroke, cancer, respiratory diseases, hypertension and kidney diseases are some of the main causes of death in Malaysia. Increased life-style diseases again lead to the rising demand for medical devices e.g. diabetics highly demand for a whole host of devices from monitoring equipment to insulin pumps. Undeniable, lifestyle diseases are also global
issues. Thus, provide Malaysia a long-term opportunity for medical devices exports as well.

(iii) Increasing Number of Healthcare Providers

Malaysia operates under a two-tier healthcare system, consisting of a government-run universal healthcare system (public sector) and a co-existing private healthcare system (private sector). Based on “Health Facts 2013” published by MoH, Malaysia has a total number of 356 hospitals as of 31 December 2012 (147 public hospitals & 209 private hospitals). Both the private and public healthcare sectors are still gradually expanding in terms of number of hospitals, with an estimated average annual growth rate of 2.4% and 2.6%, respectively. Therefore, the increasing number of healthcare providers provides a growing customer base for the Malaysia’s medical devices industry. Besides, an increasing number of private hospitals are participating in healthcare tourism, which is likely to increase the demand for high-value medical devices. As the domestic market shifts to focus more in higher value-added medical devices, it will definitely provide a cost-advantage for both hospitals and manufacturers.

iii. Government support

Under the NKEA, the Malaysian government has identified medical devices as one of the important industry that can contribute to the national economic growth. A total of 7 medical device related EPPs were specifically formulated to drive growth in the medical devices industry. The Malaysian government targets to generate about RM11.4 billion GNI under medical devices and create 86,000 job opportunities by 2020.

iv. New Scientific and Technological Developments

Scientific and technological advances are facilitating the integration of drugs and bio-logics into intelligent devices, thus driving rapid changes or innovations in the medical devices industry. Such rapid scientific and technological development is going to require a large number of qualified personnel in the field of bio-medical engineering, computer science, healthcare and related areas. Selangor state itself is currently home to more than 100 institutions of higher learning, producing a large amount of graduates in different fields.
v. Growing Supporting Industries

Malaysia has great potentials to transform into a Medical Devices Hub for both R&D and manufacturing as it is strongly supported by a growing network of suppliers from supporting industries. These industries include:
- Machinery and Equipment (M&E) Industries
- Engineering Supporting Industries
- Electronic Manufacturing Services
- Sterilisation Services: e.g. Synergyhealth, Stereo, Nuklear Malaysia
- Packaging: e.g. SteriPack, Bemis
- Biocompatibility and Clinical Trial: e.g. UKM, Info Kinetics
- Education or Training Industries

The availability of these supporting industries has further enhanced Malaysia's position as an outsourcing destination and global supplier of raw materials for medical devices manufacturers.

(2) Trends & Developments

As described above, domestic medical devices manufacturers are gradually shifting towards higher value added medical devices or the ecosystem surrounding the sector due to changing global environment and increasing competition. Therefore, medical device companies are expected to reformulate their business structures and strategies to maintain sustainability. Possible changes include company restructuring, strategic alliances, outsourcing of non-core activities etc. The current trends and developments of the medical devices industry can be summarised based on related EPPs, which the Malaysian government is actively promoting:

<table>
<thead>
<tr>
<th>Trends &amp; Developments</th>
<th>Government Project</th>
<th>Project Owners</th>
<th>Objectives</th>
<th>Current progress</th>
<th>Potential for Selangor</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD Industry</td>
<td>EPP 7 (Nationwide)</td>
<td>Penang: Medical Innovation Ventures Sdn Bhd (Mediven)</td>
<td>Upscale Malaysia’s IVD industry and help to raise the country’s IVD profile globally, starting with developing countries</td>
<td>Mediven announced a RM8.92 million investment in its IVD project</td>
<td><img src="image" alt="Green" /></td>
</tr>
<tr>
<td>Core Single Use Device (SUD) Products</td>
<td>EPP 8 (Nationwide)</td>
<td>Penang: 1. Vigilenz Medical Devices Sdn Bhd 2. Karl Mueller Scientific Sdn Bhd</td>
<td>Malaysia as the preferred supplier of high-quality contract manufacturing for SUDs</td>
<td>1. Vigilenz will invest RM25.8 million under Project EXDEV for R&amp;D to extend its current product line 2. Mueller Scientific Sdn Bhd will invest RM1.4 million to produce single-</td>
<td><img src="image" alt="Green" /></td>
</tr>
</tbody>
</table>
4. Incentives for Investments

(1) Incentives for Medical Devices Testing Laboratories

Medical devices testing laboratories have been identified as an important support service in ensuring that locally manufactured medical devices are of high quality and of international standards. Investors always need to
keep in mind that Malaysia offers a range of investment incentives for companies introducing new products, manufacturing methods as well as shifting their headquarters or manufacturing facilities to Malaysia (http://www.mida.gov.my/env3/index.php?page=incentives-for-investment). The following incentives are additionally meant to support the medical device industry and highly sophisticated medical services.

i. Companies Investing in New Testing Laboratories for Testing Medical Devices

Companies investing in setting up new laboratories are eligible for the following incentives:

a. Pioneer Status with income tax exemption of 100% of the statutory income for five years. Unabsorbed capital allowances as well as accumulated losses incurred during the pioneer period can be carried forward and deducted from the post pioneer income of the company; or

b. Investment Tax Allowance (ITA) of 60% on the qualifying capital expenditure incurred within five years. The allowance can be offset against 100% of the statutory income for each year of assessment. Any unutilised capital allowances can be carried forward to subsequent years until fully utilised.

Applications received by 31 December 2012 are eligible for this incentive.

ii. Companies Upgrading Existing Testing Laboratories for Testing Medical Devices

Companies investing in upgrading existing laboratories are eligible for an Investment Tax Allowance (ITA) of 60% on the qualifying capital expenditure incurred within five years. This allowance can be offset against 100% of the statutory income for each year of assessment. Any unutilised capital allowances can be carried forward to subsequent years until fully utilised.

Applications received by 31 December 2012 are eligible for this incentive.

Applications should be submitted to MIDA.
(2) **Exemption from Import Duty on Imported Medical Devices for Purpose of Kitting**

To encourage local manufacturers of medical devices to kit their products to add value as well as to enhance their competitiveness, full import duty exemption is given on medical devices that are imported for the purpose of kitting or producing complete procedural sets, provided these medical devices are not manufactured locally.

Applications should be submitted to MIDA.

(3) **Double Deduction for the Promotion of Exports**

Certain expenses incurred by resident companies in seeking opportunities to export Malaysian manufactured and agricultural products and services, qualify for double deduction.

The eligible expenses are those incurred in:

- overseas advertising, publicity and public relations work
- supplying samples abroad, including delivery costs
- undertaking export market research
- preparing tenders for supply of goods overseas
- supplying of technical information abroad
- preparing exhibits and participation costs in trade/industrial exhibitions, virtual trade shows and trade portals and fares for overseas travel by company employees for business
- accommodation expenses up to RM300 per day and sustenance expenses up to RM150 per day for company representatives who travel overseas for business
- maintaining sales offices and warehouses overseas to promote exports
- hiring professional to design packaging for exports, subject to the company using local professional services
- undertaking feasibility studies for overseas projects identified for the purpose of tenders
- preparing architectural and engineering models, perspective drawings and 3-D animations for participating in competitions at international level.
- participating in trade or industrial exhibitions in the country or overseas
- participating in exhibitions held in Malaysian Permanent Trade and Exhibition Centres overseas
Partnerships and sole proprietorships registered with the Companies Commission of Malaysia are also eligible for the above incentive. To qualify, they must provide the following professional services:

- legal
- accounting (including taxation and management consultancy)
- architectural (including town planning and landscaping)
- engineering and integrated engineering (including valuation and quantity surveying)
- medical and dental

For pioneer companies, the deduction is accumulated and allowed against the post pioneer income.

5. **Why Invest in Selangor?**

![Central Location in Malaysia & ASEAN](image)

![Excellent Logistics Facilities](image)

![Strong Supporting Industries](image)

![Beneficial Government Projects](image)

![Quality Workforce Available](image)

![Well-educated & Multi-lingual](image)

**Picture 5: Key Benefits to Invest in Selangor, Source: SSIC 2013**

This section is intended to provide and overview and introduction into the Selangor medical devices industry structure with reference to the members’ information provided by AMMI. AMMI has a total number of 44-member companies located in Selangor, Penang, Kedah, Perak, Perlis and Johor. Out of which most of the members are located in Selangor and are mainly involve in the manufacturing of consumables.
Chart 5: Share of AMMI Members by State, Source: AMMI 2013

Chart 6: Medical Devices Industry in Selangor, Source: AMMI, SSIC 2013

* Consumables include glove, contraceptives, catheters, woundcare, orthalmology, IVD, SUD etc.

(1) Social and Demography

Selangor being the most populous state with 5.6 million citizens and furthermore bordering the Federal Territories of Kuala Lumpur (1.7 million) and Putrajaya (0.1 million), the healthcare sector in Selangor serves the highest population density in Malaysia.
According to 2010 statistics by Department of Statistics Malaysia, apart from the “city-states” Kuala Lumpur and Putrajaya with a 100% urbanisation, Selangor (91.4%) is known for the highest degree of urbanisation in a territorial state. As mentioned earlier, 2.6 million people are expected to move from rural areas to urban areas in Malaysia between 2013 and 2018, for which Selangor with its vast economy and proximity to the commercial hub of Kuala Lumpur will be a main focus area.

In terms of healthcare, the region is experiencing typical challenges such as aging population, busy lifestyle, increasing lifestyle diseases, which will continuously increase the demand for medical devices.

### (2) Strategic Location of Selangor

ASEAN Economic Community and further agreements on investment policies such as ACIA will standardise requirements to enter neighbouring markets, for both trade and investment. In addition, ASEAN is also highly promoting harmonisation of the standards within the 10-member countries region to complement and facilitate the objective of ASEAN Free Trade Area (AFTA). Consequently, Selangor being strategically located in the heart of Malaysia and ASEAN offers easy and convenient access to all regional market. Selangor can be a springboard and regional hub due to a stable political environment, excellent infrastructure and well-educated multi-lingual workforce.

Selangor also offers the best logistics facilities in Malaysia by housing Malaysia’s largest port (Port Klang) and two major airports including the
largest international airport of the country. (Kuala Lumpur International Airport (KLIA) and Sultan Abdul Aziz Shah Airport or Subang Skypark).

(3) Government Projects in Selangor

A total of 7 medical devices EPPs were formulated to drive growth in the medical devices industry, in which 6 projects are designed for nationwide purpose. According to the latest information, Selangor has participated in 3 out of 6 EPPs. Since the projects are designed for the whole Malaysia, it is certain that the potentials of Selangor will drive additional investments and attract more industry players to invest in the state.

(4) Promising Local Customer Base

The increasing number of hospitals in Malaysia provides a growing local customer base for the medical devices industry. In Malaysia, majority of the hospitals and beds are concentrated in Selangor, Johor, Federal Territories of Kuala Lumpur and Putrajaya. In short, Selangor in close proximity to Kuala Lumpur and Putrajaya simply means that it caters to the demand of most hospitals in Malaysia for all kinds medical devices.

![Image showing hospitals and beds statistics]

Picture 7: Key Facts of Healthcare Sector in Klang Valley (2011), Source: Clinical Research Centre 2012

(5) Strong Supporting Industries

i. Education and Training Industries

Selangor has more than 100 institutions of higher learning producing between 10,000 and 20,000 graduates in different fields every year. However, Malaysia only has 15 education or training institutions, which offer different levels of medical device related qualifications, ranging from certificate to doctorate
level. Some institutions even provide short courses or up-skilling programmes. To further address and service human capital needs of the investors, MIDA established an Industry Talent Management Division in January 2013.

E.g.: Universiti Kebangsaan Malaysia (UKM), Universti Malaya (UM) and Neville Clarke (Malaysia) are located in Klang Valley area.

ii. Other related Industries

Selangor currently has an established rubber industry, manufacturing and supplying an entire downstream of rubber products to industries from both local and overseas market.

With a number of electronics manufacturing services (EMS) companies located in Selangor, the E&E industry performance here is fairly strong. These companies provide essential supports to several industries in Malaysia e.g. semiconductor, industrial electronics, consumer electronics and medical devices etc.

On the other hand, sterilisation services (e.g. gamma, electron beam and ethylene oxide) are available in Selangor as well. Major sterilisation companies like Synergyhealth, Stereo and Sterilgamma are located in Selangor. Government-owned irradiation facilities – MINTec-Sinagama and Malaysian Nuclear Agency are also situated here.

For medical device packaging, Selangor has well-established companies e.g. Bemis and SteriPack. In addition, UKM in Selangor also provide biocompatibility and clinical trial services.
6. **Main Sources**

- Medical Device Authority: [http://www.mdb.gov.my](http://www.mdb.gov.my)
- Malaysia Medical Device Association: [http://www.mmda.org.my](http://www.mmda.org.my)
- ASEAN Federation of Medical Device Industry: [http://www.aseanmed.org](http://www.aseanmed.org)
- Medical Device Summit: [http://www.medicaldevicesummit.com](http://www.medicaldevicesummit.com)
- Malaysian-German Chamber of Commerce and Industry: [http://www.malaysia.ahk.de/](http://www.malaysia.ahk.de/)
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- The Western Cape Destination Marketing, Investment and Trade Promotion Agency – South Africa: [http://wesgro.co.za](http://wesgro.co.za)
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- Business Wire: [http://www.businesswire.com](http://www.businesswire.com)
- Nobles Global Communications: [http://www.noblesgc.com](http://www.noblesgc.com)
- PR Newswire: [http://www.prnewswire.com](http://www.prnewswire.com)